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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,380	08/27/2003	Buchi Reddy Reguri	U 014781-0	4571

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EXAMINER

REYES, HECTOR M

ART UNIT PAPER NUMBER

1625

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,380

Applicant(s)

REGURI ET AL.

Examiner

Hector M Reyes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/05/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☒ Claim(s) 30-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of The Claims

Claims 1-33 are under Examination.

Priority Document

On page 1 of the instant specification, it is said that the instant Application claim priority of the Indian Patent Application No. 631/MAS/2002. However, there is no certified copy of the said Application in the record.

Specification Objection

On page 1 of the instant specification it is indicated that nateglinide is also known chemically as N-(trans-4-isopropylcyclohexanecarbonyl)-D-phenylalanine. However, on page 4 of the specification a chemical structure is shown for the said compound that does not represent the chemical name described in page 1.

Claims Objections

Claims 31-33 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33 are indefinite because it is not clear if the said claims are directed to a process of making or to the product obtained by a particular process. Clarification is hereby requested. Applicants are advised that product by process claims are improper whenever the obtained product can be defined in terms of its known structure. The chemical structure of nateglinide is well known in the art, thus the said claims are considered improper and any reference teaching the said compound would anticipate the said claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumikawa et al, US patents 5463116 or 5488150.

Sumikawa discloses crystal structures of N-(trans-4-isopropylcyclohexanecarbonyl)-D-phenylalanine, having the chemical structure displayed in column 1 in both cited patents. The said crystals are said to have a therapeutic utility in depressing blood glucose levels, see for example US 5463116, column 1, lines 19-23. Thus, the said substance is said to be suitable for use in medicines than those of other crystals forms, see 5463116, column 1, lines 65-67.

Sumikawa also teaches a method for the production of the said crystals comprising:

- Dissolution of the compound in different physical forms, such as amorphous or other crystal forms, in an organic solvent and effecting crystallization "in several ways as will be apparent to those of skill in the art" see column 4, lines 1-46 wherein variants of the crystallization method is disclosed.

Sumikawa discloses toluene among one of the preferred organic solvents used in the crystallization method, see column 4, lines 34.

Sumikawa does not disclose:

- The crystal X form of N-(trans-4-isopropylcyclohexanecarbonyl)-D-phenylalanine
- Compositions comprising the said particular crystal form or
- A method for the preparation of the preparation of the said particular form.

However, the said X crystal form, pharmaceuticals compositions comprising the same and method of preparation of the said form results obvious to those of skill in the art

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under the meaning of 35 USC 103 since a modified physical form of a compound which existed in another form in the prior art requires a substantial difference in their utilities and must be unobvious. Absence any showing that the claimed X form is unobvious over the crystalline forms disclosed by Sumikawa, a person skill in the art would be motivated to prepare other polymorphs of the same compounds using crystallization techniques as the ones disclosed by Sumikawa in order to obtained polymorph of the same substance and further use the said substance in pharmaceutical compositions directed to lower the glucose levels in the blood, as already taught in the prior art.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hector M. Reyes, whose telephone number is (571) 272-0691. The Examiner can normally be reached Monday through Friday from 8:30 to 4:30pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Ms. Rita Desai can be reached at (571) 272-0684.

Hector M. Reyes, PhD JD
Reg # P-54,846
AU 1625
June 25, 2004


PAUL J. KILLOS
PRIMARY EXAMINER